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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,682	04/04/2001	Elena Feinstein	65503-B/JPW/MS	3555
7590 05/10/2004			EXAMINER	
John P. White Cooper & Dunham LLP 1185 Avenue Of the Americas New York, NY 10036			JOHANNSEN, DIANA B	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary**Application No.**

09/825,682

Applicant(s)

FEINSTEIN ET AL.

Examiner

Diana B. Johannsen

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003 and 09 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,24,26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,24,26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0903</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

1. This action is in response to the Amendment and Response filed September 12, 2003, and to the Amendment and Response to Notice of Non-Compliant Amendment (including a complying complete set of claims) filed January 9, 2004. Claims 1-2, 4-6, and 26-27 have been amended, and claims 7, 9-23, 25, and 28-29 have been canceled. Claims 1-2, 4-6, 24, and 26-27 are now pending and under consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections and objections not reiterated in this action have been withdrawn as being obviated by Applicants' amendments. **This action is FINAL.**
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

3. It is noted that claims 10-23 and 25 (which were previously withdrawn from consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention) have now been canceled. Applicant timely traversed the restriction (election) requirement in the Communication of December 2, 2002. It is also noted that the remaining claims have been amended such that the claims now only recited elected SEQ ID Nos 57, 56, and 41. Applicant timely traversed the restriction (election) requirement with regard to election of a combination of sequences in the Communication of March 24, 2003.

Information Disclosure Statement

4. Regarding the IDS filed September 12, 2003 (a copy of which was also filed on January 9, 2004), it is noted that the "American Cancer Society" reference could not be considered because no copy of the reference was provided, either in the instant application or in application no. 09/670,672. It is also noted that as the IDS filed January 9, 2004 is a duplicate of that filed September 12, 2003, only a single copy of the 1449 has been signed/initialed and provided herewith.

Claim Rejections - 35 USC § 112

5. In view of the cancellation of claims 7, 9, and 28-29, the rejections of those claims under 35 U.S.C. 112 set forth in the prior Office action are moot.

6. Claims 1-2, 4-6, 24, and 26-27 are rejected under 35 U.S.C. 112, first paragraph, for lack of enablement, for reasons stated in the Office action of June 16, 2003. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is first noted that Applicants' amendments have overcome the instant rejection in part. Particularly, the pending claims no longer encompass detection of the sequences of the claims as indicators of stage Ta and/or stage T1 bladder cancer/TCC. However, the claims as written encompass detection of increased expression of molecules other than SEQ ID Nos 56, 57, and 41, and continue to encompass diagnosis of bladder cancer in non-human patients. Accordingly, the claims lack enablement for reasons stated in the prior Office action, which reasons are repeated below.

First, it noted that the prior Office action stated that:

The specification teaches that the genes corresponding to SEQ ID NOS 56, 57 and 41 “were found to be upregulated in at least 60% of TCC samples and unchanged in at least 75% of the normal samples” (p. 40), and provide evidence that SEQ ID Nos 56, 57, and 41 are upregulated in many bladder TCC samples as compared to healthy controls (see Tables 1 and 2),

and that

Accordingly, the teachings of the specification indicate that the levels of expression of SEQ ID NOS 56, 57 and 41 are frequently elevated in bladder TCC tissues, and thus increased expression of these genes/molecules is one factor that one of skill in the art would reasonably consider in diagnosing bladder cancer/bladder TCC.

However, the instant claims as amended are not limited to increased expression of SEQ ID Nos 56, 57, and 41; note e.g., items (b) and (c) of claim 1, which encompass a variety of other molecules. Furthermore, as was stated in the prior Office action, the specification does not provide evidence of “an association between expression of any of these polynucleotides [i.e., SEQ ID Nos 56/57/41] and cancer of any type in non-human patients.” However, the claims as amended continue to encompass any type of “subject.” The prior Office action also noted that the teachings of the prior art did not enable the invention beyond what is enabled by the teachings of the specification. Accordingly, for reasons stated in the prior Office action, it would require undue experimentation to make and use Applicants’ invention in a manner reasonably commensurate with the claims.

It is noted that the response indicates that Applicants believe the rejection has been overcome, noting that “All the pending claims as currently amended....relate to methods of diagnosing bladder cancer using polynucleotides which include sequences corresponding to SEQ ID NOS. 56, 57 and 41.” However, the prior action indicated that

the claims were enabled with respect to expression levels of SEQ ID Nos 56, 57, and 41, not for methods in which sequences "corresponding to" these sequences are employed. Further, the response does not address the issue of non-human subjects or patients. Accordingly, Applicants' arguments are not persuasive, and this rejection is maintained.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:

7. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is noted that the claim has been amended to recite "the determining step" in lieu of "the analysing step," thereby overcoming a rejection made in the prior Office action. However, the "determining" step of claim 1 does not refer to a single "polynucleotide," but only multiple "polynucleotides." Accordingly, the recitation "said polynucleotide" in claim 6 lacks antecedent basis.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Diana B. Johannsen
Patent Examiner
May 4, 2004



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5/5/04